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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,437	10/15/2001	Jeffrey A. Heroux	2528-8	3932
22852	7590	10/19/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/976,437	<b>Applicant(s)</b> HEROUX ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 45-80 is/are pending in the application.
- 4a) Of the above claim(s) 77-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1045101</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicant's election with traverse of Group II, claims 45-76 is acknowledged. Applicant's election with traverse of Group II (claims 45-76) in the reply filed on May 24, 2004 is acknowledged. The traversal is on the ground(s) that Group I -III are related and would not be a serious burden to search them together. Applicants' arguments are fully considered and found persuasive in part. Group I and II will be rejoined herein for the purpose of examination of both the groups together. However, the invention in Group III is independent and distinct as discussed in the restriction requirement. Further, (i) search for one group does not necessarily result in art related to another group (ii) separate classification search is prima facie evidence of burden, (iii) the issues are not the same with respect to 35 U.S.C. 112 and 35 U.S.C. 101 statutes, Further, The Group III is patentably distinct as far as the subject matter is concerned, because invention of Group I and II are directed to method, and invention in Group III is directed to a kit (product), which can be used in a materially different process as discussed in the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

2. The Information Disclosure Statement filed on 10/15/2001 has been entered and considered.
3. This application filed on 10/15/2001 is a divisional of US non-provisional 09/157,808 filed on 9/17/1998.
4. Claims 45-76 are considered for examination Claims 77-80 are withdrawn from further consideration in view of restriction/election, as being non-elected claims. This is made FINAL.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47, 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 47 recites "A:B linkage", which is unclear and indefinite because it is not clear what A and B encompasses, does it refer to avidin: biotin linkage or does it refer to alphabet A and B. Amendment to recite the specific linkage would obviate the rejection.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 45-47, 50, 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Leland et al. (EP 0 570518).

Leland et al. teach a method of claims 45-46, of assaying a sample for an activity (binding activity) that joins (binds) a first substrate (an assay-performance substance) and a

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second substrate (a particle capable of binding with the sample analyte) to form a product (binding complex) comprising:

- (a) forming a composition comprising said sample, said first and second substrate (see page 6, lines 10-19);
- (b) incubating said composition to form said product (see page 6, line 21);
- (c) immobilizing a luminescent label linked to said product on an electrode (see page 6, lines 22-23);
- (d) applying a voltage at said electrode to induce luminescent label to emit luminescence (see page 6, line 23-24);
- (e) measuring emitted luminescence to measure said activity (see page 6, line 25-26).

With regard to claim 46, Leland et al. teach that said first substrate is linked to a luminescent label (see page 9, line 48-58, page 10, line 1-7) and said second substrate linked to electrode (magnetically responsive particles) (see page 10, line 56-58, page 11, line 1-7);

With regard to claim 47, 50, Leland et al. teach that the second substrate is linked to said electrode via avidin (capture moiety) biotin linkage (see page 15, line 44-46);

with regard to claims 52-53, Leland et al. teach that said first substrate comprises peptides and nucleic acids (see page 9, line 48-57). Thus the disclosure of Leland et al. meets the limitations in the instant claims.

B. Claims 45-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Massey et al. (USPN. 5, 866,434).

Massey et al. teach a method of claims 45-46, 50, of assaying a sample for an activity (binding activity) that joins (binds) a first substrate (an assay-performance substance) and a

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second substrate (a functionalized graphic nanotube) to form a product (binding complex)

comprising:

(a) forming a composition comprising said sample, said first and second substrate (see col. 13, line 9-19, line 31-43);

(b) incubating said composition to form said product (see col. 13, line 20-22, line 44-45);

(c) immobilizing a luminescent label linked to said product on an electrode (see col. 13, line 15-22, line 31-45);

(d) applying a voltage at said electrode to induce luminescent label to emit luminescence (see col. 13, lines 24-27, line 48-51);

(e) measuring emitted luminescence to measure said activity (see col. 13, line 29-31, line 52-54).

With regard to claim 46, Massey et al. teach that said first substrate is linked to a luminescent label (see col. 13, line 15-17) and said second substrate linked to electrode (magnetically responsive nanotubes) (see col. 13, line 18-19);

With regard to claim 47, 50, 57, 60, Massey et al. teach that the second substrate is linked to said electrode via avidin (capture moiety) biotin linkage (see col. 40, line 41-50);

With regard to claims 48-49, Massey et al. teach that said electrode (nanotube fibrils) linked to one or more additional substrates comprising at least two substrates that differ in structure (see col. 52, line 27-67, col. 53, line 1-2, wherein nanotube fibril comprises biotinylated fibril and alkylated biotinylated fibrils having two different structures);

With regard to claims 52-53, 62-63, Massey et al. teach that said first substrate comprises peptides and nucleic acids (see col. 16, line 45-64);

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With regard to claim 51, 61, 70-71, Massey et al. teach that said activity (binding activity) results in the formation of a covalent bond (see col. 10, line 13-37, wherein the complex formed with Y indicates a covalent bond);

With regard to claim 55, 60, Massey et al. teach

(a) forming a composition comprising said sample and said substrate (see col. 14, line 20-28);  
(b) incubating said composition under conditions wherein said activity can cleave said substrate (see col. 14, line 30-31);

(c and d) immobilizing a luminescent label on an electrode (nanotube) and separating said substrate from said composition by inducing luminesce (see col. 14, line 25-34);

(e) measuring emitted luminescence to measure the activity (see col. 14, line 35-36).

With regard to claim 65-66, 72-73, said electrode comprises elemental carbon in the form of graphite (see col. 13, line 18-19);

With regard to claim 67, 74, Massey et al. teach said electrode comprises conductive particles with in or on a polymeric material (see col. 11, line 47-67, col. 12, lines 1-28);

With regard to claims 54, 64, 68, 75, Massey et al. teach that said activity is an enzyme activity comprising catalytic enzymes as glucosidases, dehydrogenases (see col. 47, line 10-15, col. 49, line 55-67, col. 50, line 1-67);

With regard to claims 69, 76, Massey et al. teach that the method further comprises an inhibitor (reductant) (see col. 14, line 3).

Thus the disclosure of Massey et al. meets the limitations in the instant claims.

### ***Conclusion***


No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 . The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
October 14, 2004

  
JEFFREY FREDMAN  
PRIMARY EXAMINER

10/15/04